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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,814	02/27/2004	John G. Babish	068911-0075	5630

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EXAMINER	
KANTAMNENI, SHOBHA	
ART UNIT	PAPER NUMBER
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/789,814	BABISH ET AL.	
	Examiner	Art Unit	
	Shobha Kantamneni	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *NONE* is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment filed on 01/03/2007, wherein claims 1, and 7 have been amended.

The rejection of Claims 1-7 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-115 of copending Application No. 10/464410; the rejection of claims 4-7 as being unpatentable over claims 1-34 of copending Application No. 10/464834; the rejection of claims 1-3 as being unpatentable over claims 1-12 of copending Application No. 10/689856; unpatentable over claims 1-6 of copending Application No. 10/774048 is MAINTAINED. Note: Applicants offer to submit and accept terminal disclaimers linking any of the cited copending applications to the instant application should the instant case proceed to allowance.

Applicant's amendment has overcome the rejection of claim 7 under 35 U.S.C. 112 first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's arguments have been fully considered, but not found persuasive, and the rejection of claims 1-3 under 35 U.S.C 102(e) as being anticipated by Shahlal et al. (US 6,583,322, PTO-892) is MAINTAINED. See under response to arguments.

Applicant's arguments have been fully considered, but not found persuasive, and the rejection of claims 4-7 under 35 U.S.C. 103(a) as being

unpatentable over Tobe (US 5,604,263, PTO-892) is MAINTAINED. See under response to arguments.

Claims 1-7 are pending.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3 is rejected under 35 U.S.C 102(e) as being anticipated by Shahlal et al. (US 6,583,322, PTO-892).

Shahlal et al. discloses compositions comprising a reduced isoalpha acid (RIAA) and isoalpha acid (IAA). Isoalpha acids include isohumulone, isocohumulone, isoadhumulone, reduced isoalpha acid disclosed therein include dihydro isoalpha acids (DHIA), and hexahydro isoalpha acids ((HHIA). See abstract; FIG.1; FIG.2; column 1, lines 14-24.; lines 60-63; column 4, lines 2-25. It is also disclosed that compositions therein which are mixtures of DHIA, and IAA remained clear liquids at all ratios between about 1 and 99 %., and comprise at least 0.1 % of the composition. See column 18, lines 15-45

Thus, Shahlal et al. anticipates instant claims 1-3.

Response to Applicant's Arguments:

Applicant argues that "The only specific ratio information provided in Shahlai are those presented in Table 5-1, at column 18. Out of eight mixtures (1-8) shown, none of which being a mixture of IA and DHIA, only mixtures 1, 3, and 4 disclose specific ratios of IA and THIA (a reduced isoalpha acid). However, even there, the disclosed range for THIA (40-70 %) falls significantly out of the range of RIAA presently claimed (about 10 to 33%)". This argument has been fully considered, but not found persuasive because the instantly claimed ratio of 3:1 to about 1:10 of RIAA : IAA corresponds to 75 % to about 50 % of RIAA. Thus, the disclosed range of THIA (40 to 70 %) by Shahlai et al. falls in the instant claimed range of RIAA. Thus, mixtures 1, 3, and 4 disclosed by Shahlai anticipates instant claims.

Applicant argues that "Shahlai neither specifically indicates the claimed ratios of the isoalpha acids and reduced isoalpha acids nor in any way suggests that the specific ratios would be advantageous in reducing PGE2 mediated inflammation." This argument has been considered, but not found persuasive as discussed above, and further the recitation of the intended use of the claimed invention such as "for reducing PGE2 mediated inflammation", is not considered to limit the composition claims herein so long as the prior art discloses the same composition comprising the same compounds, in an effective amount, as the

instantly claimed.. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tobe (US 5,604,263, PTO-892).

Tobe teaches a method of treating inflammatory disorder osteoporosis, comprising administering a pharmaceutical composition comprising an effective amount of one or more compounds selected from alpha acids, isoalpha acids and derivatives contained in hop extract such as isohumolone, isocohumolone, and isoadhumulone of the instant claims. See abstract; column 2, structures (IV) to (VI), lines 64-67; column 8, claim 1-4. It is also taught that isoalpha acid derivatives contained in hop extracts have a similar structure to that of prostagladin E2, namely 5-membered ring with an unsaturated carbonyl group, and are useful for treating PGE2 mediated inflammation. It is further taught that the isoalpha acid derivatives inhibit bone resorption at a concentration of as low as $1x10^{-9}$ M. See column 2, line 54-column 3, line 30.

Tobe does not teach the employment of reduced isoalpha acid such as dihydro-isohumulone, dihydro-isocohumolone, and dihydro-adhumulone in the method therein.

Tobe does not expressly teach the ratio of reduced isoalpha acid to isoalpha acid compounds as about 3:1 to about 1:10.

It would have been obvious to a person of ordinary skill in the art to employ reduced isoalpha acid in the method of treating inflammatory disorder osteoporosis because Tobe teaches that compounds which has structure similar to that of prostagladin E2 are useful in treating PGE2 mediated inflammation, and reduced isoalpha acid has a structure similar to that of prostaglandin E2, and further reduced isoalpha acid is a derivative of isoalpha acid which is used for treating inflammatory disorder. Thus, one of ordinary skill in the art at the time of invention would have been motivated to employ reduced isoalpha acid such as dihydro-isohumulone in combination with isoalpha acid with reasonable expectation of treating PGE2 mediated inflammation.

It would have been obvious to a person of ordinary skill in the art at the time of invention to determine or optimize parameters such as effective amounts of the reduced isoalpha acid: isoalpha acid employed in the composition of Tobe, to treat osteoporosis.

One having ordinary skill in the art at the time the invention was made would have been motivated to determine the effective amounts of compounds such as reduced iso-alpha acids, and iso-alpha acids employed in the pharmaceutical compositions for methods of reducing inflammation in which the

ratio of two compounds is about 3:1 to about 1:10, since the optimization of effective amounts to be administered, is considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art.

It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Response to Applicant's Arguments:

Applicant argues that "The Application identifies certain ratios having qualities (foremost synergy) not previously known or suspected. The composition and method of the invention stem from the identification of synergistic ratios of reduced isoalpha acids and isoalpha acids which are neither taught or suggested by the prior art." This argument has been fully considered, but not found persuasive because the instant claims are not drawn to a synergistic effect by employing synergistic ratios of reduced isoalpha acids and isoalpha acids, but drawn to a ratio of about 3:1 to about 1:10 of RIAA and IAA. Thus, it one having ordinary skill in the art at the time the invention was made would have been motivated to determine the effective amounts of compounds such as reduced iso-alpha acids, and iso-alpha acids employed in the pharmaceutical compositions for methods of reducing inflammation in which the ratio of two compounds is about 3:1 to about 1:10, since the optimization of effective amounts to be administered, is considered well in the competence level of an

ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period, will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-Tuesday, Thursday-Friday, 8am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, Ph.D can be reached on 571-272-

0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shobha Kantamneni, Ph.D
Patent Examiner
Art Unit : 1617

SUPERVISORY PATENT EXAMINER